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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Elaine Lee

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EXAMINER

ARAJ, MICHAEL J

ART UNIT

PAPER NUMBER

3775

MAIL DATE

DELIVERY MODE

04/18/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/749,980	Applicant(s) LEE, ELAINE	
	Examiner MICHAEL ARAJ	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-11,14-16,19,22-24,31,32 and 34-37 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,22,31,32 and 34-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 7-11, 14-16, 19, 23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/15/10;10/15/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The previous rejection has been withdrawn after discussions made during the pre-appeal conference on January 18, 2011. The new non-final rejection follows.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 7-11, 14-16, 19 and 23-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claim 1, line 4, "balloons coated with iron microspheres" is unclear to what the applicant means. Are the balloons another structure in conjunction with the vaso-occlusive coil or is it another bioactive material. Either way, there isn't proper description of this balloon coated with iron microspheres.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 11 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Matterson (U.S. Patent No. 4,530,113).

Matterson discloses a vaso-occlusive composition consisting of a vaso-occlusive coil (10) and a bioactive material selected from the group consisting of fibrin; polyethylene glycol derivatives; thrombin-coated gelatin granules; balloons coated with iron microspheres; trace metals; thrombus-stabilizing molecules; and combinations thereof, wherein combinations of bioactive materials are not contained in separate layers. The bioactive materials contained are fibrin (column 1, lines 53-57) and a polyethylene glycol derivative (column 6, paragraph 2). The bioactive material (fibrin) is adsorbed to the vaso-occlusive coil (column 1, paragraph 5).

Matterson also inherently discloses a method of occluding a vessel comprising administering to a subject in need thereof a vaso-occlusive composition according to claim 1. The occlusion of the vessel occurs during implantation of the vaso-occlusive coil. The vessel must be clamped at one end in order to be able to attach the coil without losing large amounts of blood. Once the coil fully attached the vessel is unclamped and the blood is allowed to flow.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to

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a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-10 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matterson (U.S. Patent No. 4,530,113) in view of Schwarz et al. (U.S. Patent No. 4,414,976).

Matterson discloses the claimed invention except the for using thrombus-stabilizing molecule that is a plasminogen activator inhibitor or plasmin inhibitor. Schwarz teaches that tissue adhesive for use in vascular surgery may be made with Factor XIII, plasminogen activator inhibitor or plasmin inhibitor in order to stimulate wound healing (Column 1 lines 37-44). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Matterson with the thrombus-stabilizing molecule being plasminogen activator inhibitor or plasmin inhibitor, in view of Schwarz, in order to promote healing of the graft.

Claims 14 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matterson (U.S. Patent No. 4,530,113) in view of in view of Eder et al. (U.S. Patent No. 5,980,550).

Matterson discloses the claimed invention except for the coil being plasma treated and subjected to ion implantation. Eder et al. disclose the coil being plasma treated (Col. 3, Paragraph 2), subjected to ion implantation (Col. 6, Paragraph 6). It would have been obvious to one skilled in the art at the time the invention was made to the device of Matterson subjected to being plasma treatment and ion implantation in view of Eder et al., in order to promote healing.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matterson (U.S. Patent No. 4,530,113) in view of Nikolchev et al. (U.S. Patent No. 6,526,979).

Matterson discloses the claimed invention except for the vaso-occlusive coil being microtextured. Nikolchev discloses that an occlusive coil is microtextured in order to promote tissue ingrowth (column 14, paragraph 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Matterson with the microtexturing in view of Nikolchev, in order to enhance tissue ingrowth and healing of the vessel.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matterson (U.S. Patent No. 4,530,113) in view of Soykan et al (U.S. Patent No. 6,206,914).

Matterson discloses the claimed invention except for wherein the occluding of a vessel is an aneurysm. Soykan et al. discuss providing an implantable system for the treatment of a variety of disorders, such as, coronary artery disease, which can be manifested by stenosis, myocardial infarction, aneurysm, angina, and/or atherosclerosis, or cerebro-vascular occlusion, which can result in a stroke, for example. (column 4, lines 17-23) Since all of these disorders can be treated with the use of an implantable system such as stents or grafts (column 4, lines 25-26) as discussed, one could apply this device that has so many benefits to the use in an aneurysm if one so desired. It would have been obvious to one of ordinary skill in the art to have developed a method of using the coil of Matterson with an aneurysm in view

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of Soykan et al. since the device would have a preventative, therapeutic, or disease-treating effect on surrounding tissue.

Response to Arguments

Applicant's arguments with respect to claims 1, 7-11, 14-16, 19, 23 and 24 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL ARAJ whose telephone number is (571)272-5963. The examiner can normally be reached on Monday-Friday 8 am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached on 571-272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael J Araj/
Examiner, Art Unit 3775

/Thomas C. Barrett/
Supervisory Patent Examiner, Art
Unit 3775